NEW ANIMAL DRUG REGULATION

New animal drugs are required to be subject to approved new animal drug applications supported by adequate safety and effectiveness data. Review of data, labeling and manufacturing controls and procedures are key elements in evaluating new animal drug applications.

I. Purpose:

To provide general references and guidance to regulation of new animal drugs.

II. Authority:

Specific sections of the law and specific regulations are cited in the guides on investigational and new animal drugs, labeling and medicated animal feeds. Key regulatory authority is as follows:

A. The Federal Food, Drug, and Cosmetic Act (FFDCA):

1. Definitions: Section 201, which defines among other things labels, labeling, new drugs, new animal drugs and animal feed.

2. Prohibited Acts: Section 301 prohibits interstate commerce of any adulterated or misbranded food, drug, device or cosmetic. It also prohibits the adulteration or misbranding of these articles while in interstate commerce or while held for sale after shipment in interstate commerce. There are numerous other prohibited acts in this section of the FFDCA.

3. New Animal Drugs: Section 512 sets forth the authority for regulating new animal drugs, including generic animal drugs, and feeds containing new animal drugs. It provides an exemption for new animal drugs intended solely for investigational use.

4. Drug Registration and Listing: Section 510 sets forth the requirements for registration of facilities and listing of drug products.

5. Adulteration and Misbranding: Sections 501 and 502 set forth the authority to deem drugs (and devices) adulterated and misbranded.

B. The rules codified under Title 21 of the Code of Federal Regulations (CFR) are intended to facilitate the enforcement of the FFDCA. Of special pertinence are:

1. Subchapter E - Animal Drugs, Feeds, and Related Products. This subchapter is the principal location of new animal drug regulations. Parts 500, 505 and 510 set forth requirements and warnings for various drugs. Parts 511 and 514 cover investigational new animal drugs and commercial marketing of new animal drugs. Parts 520-558 (except Part 556) list the approved new animal drugs including drugs for use in animal feeds. Part 556 lists residue tolerances.

2. Subchapter A - General. This subchapter contains general regulations for the enforcement of the Act. It also contains sections on environmental impact considerations, color additives, and good laboratory practices.

3. Subchapter C - Drugs: General. Regulations concerning drug labeling, drug registration/listing, good manufacturing practice and other requirements are found in this chapter.

III. Generic Equivalent Drugs:

This includes those drugs that are generic to an NAS/NRC efficacy reviewed drug, i.e., a drug which was originally approved on the basis of safety only prior to October 10, 1962, and was subsequently reviewed for effectiveness under the Drug Amendments of 1962. Bioequivalency, unless waived, must be provided to show efficacy equivalence to a reviewed drug which was either found effective by the NAS/NRC DESI review or subsequently elevated to the effective category.

On November 14, 1988, the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) (Pub. 100-670) was signed into law. Under this law, abbreviated new animal drug applications (ANADA) for generic equivalents of animal drugs approved subsequent to 1962 may be submitted. Under the provisions of GADPTRA, however, no ANADA could be approved prior to January 1, 1991. With the enactment of GADTRA, the requirements for approval of ANADAs for pre- and post-1962 drug products became the same.

IV. Color Additives:

Coloring components encountered in new drug formulations must comply with Section 706 of the Act and related regulations (21 CFR Parts 70 through 82, Color Additives.)

A. Use of Colors:

1. Provisional list: Only colors listed for drug use in the color additive regulations may be used. The regulations include a "provisional" list of colors that maybe used. These are colors that may be used pending completion of scientific investigations to determine whether such colors may be listed (more or less permanently) as suitable and safe for such use.

2. Time limitation: The provisional list includes for each color a closing date after which the color may not be used unless the date is extended or the color loses its "provisional" status and is included in the list of permitted color additives.

3. Restrictions:

a. Specific: Certain color additives are restricted in use, e.g., to specific uses of maximum amounts. Such limitations are noted in the regulations.

b. General: General restrictions, e.g., on the use of color additives in the area of the eye and in injections, appear in 21 CFR 81.

B. Certification: Color additives are subject to batch certification unless exempted by regulation.

C. Special considerations:

1. De-listing a color: Problems may be encountered when a provisionally-listed color is "de-listed" or removed from the list of colors that may be used. Approved NADAs for drugs containing such a color must be supplemented if the formulation is revised to substitute another color; pending NADAs must be amended.

2. Procedures for supplements:

Supplements providing solely for a revised formulation to delete a "de-listed" color and substitute a listed color may be handled as provided for in 21 CFR 514.8.

D. Program responsibility: Program responsibility for color additives is assigned to the Center for Food Safety and Applied Nutrition.

V. Environmental Impact:

Environmental impact requirements are covered in CVM Guide 1240.2410.